



May 17, 2005

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Ortho Molecular Products Inc.  
3017 Business Park Drive  
P.O. Box 1060  
Stevens Point, WI 54481  
715.342.9881 Phone  
800.332.2351  
715.342.9866 Fax  
orthomolecularproducts.com

Office of Special Nutritional (HFS-450)  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

MAY 25 2005

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

**Name of Manufacturer:** Ortho Molecular Products, Inc.  
3017 Business Park Drive  
P.O. Box 1060  
Stevens Point, WI 54481

**Statement Text:** Gastrointestinal Support

**Dietary Ingredients:** Biotin, L-Glutamine USP, Quercetin, N-Acetyl Cysteine USP, Bromelain (2,400 GDU/g), Gamma Oryzanol, Tumeric Root Extract (Standardized to contain 95% Curcumin), N-Acetyl-d-Glucosamine, Milk Thistle Seed Extract (Standardized to contain 80% Silymarin), Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

**Dietary Supplement Name:** Mucosagen

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager  
Document Control / Training Manager  
Ortho Molecular Products

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5/17/2005  
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## Attachment of Mucosagen Labels

**Suggested Use:** As a dietary supplement, 2 capsules three times per day or as recommended by your health care professional.  
**Formulated to be free of allergens derived from:** Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergens: Pineapple/Bromelain.  
If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion.  
**Keep container tightly closed. Store at room temperature. Keep out of reach of children.** This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.  
Label ID L-OMP100-547090-B



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Dietary Supplement Product #547

ORTHOMOLECULAR  
PRODUCTS  
Because Efficacy Matters®  
**Mucosagen**



90 Capsules

Supplement Facts	
Serving Size: 2 Capsules Servings Per Container: 45	
Amount Per % Daily	Serving Value
2 capsules contain	250 mg
Biotin	83%
L-Glutamine USP	500 mg
Quercetin	335 mg
N-Acetyl Cysteine USP	85 mg
Bromelain (2,400 GDU/g)	85 mg
Gamma Oryzanol	85 mg
Turner Root Extract	85 mg
(Standardized to contain 95% Curcumin)	
N-Acetyl-d-Glucosamine	70 mg
Milk Thistle Seed Extract	45 mg
(Standardized to contain 80% Silymarin)	
* % Daily Value not established	

†These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Mfg. by Ortho Molecular Products, Inc. 3017 Business Park Drive Stevens Point, WI 54481

OrthoMolecularProducts.com

Other Ingredients: Natural Vegetable Capsules.  
This product may contain one or more of the following:  
Ascorbyl Palmitate, Magnesium Stearate,  
Microcrystalline Cellulose and Silicon Dioxide

**Suggested Use:** As a dietary supplement, 2 capsules three times per day or as recommended by your health care professional.  
**Formulated to be free of allergens derived from:** Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. This product contains the following potential allergens: Pineapple/Bromelain.

If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion.

**Keep container tightly closed. Store at room temperature.**

**Keep out of reach of children.**

This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged.

Label ID L-OMP100-547180-B

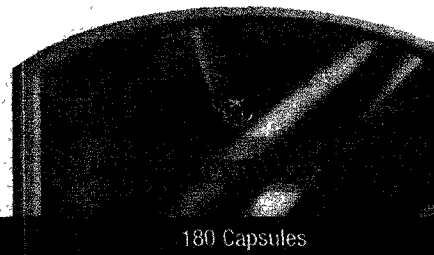


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Dietary Supplement Product #547A

ORTHOMOLECULAR  
PRODUCTS  
Because Efficacy Matters®

**Mucosagen**



180 Capsules

Ortho Molecular Products Mucosagen

5/17/200

## Supplement Facts

Serving Size: 2 Capsules

Servings Per Container: 90

2 capsules contain	Amount Per Serving	% Daily Value
Biotin	250 mcg	83%
L-Glutamine USP	500 mg	*
Quercetin	335 mg	*
N-Acetyl Cysteine USP	85 mg	*
Bromelain (2,400 GDU/g)	85 mg	*
Gamma Oryzanol	85 mg	*
Tumeric Root Extract (Standardized to contain 95% Curcumin)	85 mg	*
N-Acetyl-d-Glucosamine	70 mg	*
Milk Thistle Seed Extract (Standardized to contain 80% Silymarin)	45 mg	*

\* % Daily Value not established

Other Ingredients: Natural vegetable capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide

†These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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[OrthoMolecularProducts.com](http://OrthoMolecularProducts.com)